

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

IN RE: AFLIBERCEPT PATENT LITIGATION

MDL No. 1-24-md-3103-TSK

THIS DOCUMENT RELATES TO:

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

SAMSUNG BIOEPIS CO., LTD.,

Defendant.

Civil Action No. 1:23-cv-94-TSK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

SAMSUNG BIOEPIS CO., LTD.,

Defendant.

Civil Action No. 1:23-cv-106-TSK

**DEFENDANT SAMSUNG BIOEPIS CO., LTD.'S RESPONSE TO REGENERON'S
MOTION FOR GUIDANCE REGARDING TEMPORARY RESTRAINING ORDERS**

Defendant Samsung Bioepis Co., Ltd. (“SB”) submits this response to Plaintiff Regeneron Pharmaceuticals, Inc.’s (“Regeneron”) Motion for Guidance Regarding Temporary Restraining Orders in view of the May 18, 2024 Expiration of Regulatory Exclusivity for EYLEA®. Dkt. 36 (MDL No. 1:24-md-3103-TSK).

I. A TRO MOTION IS UNNECESSARY BECAUSE REGENERON IS NOT ENTITLED TO INJUNCTIVE RELIEF

With Regeneron’s fully briefed preliminary injunction (“PI”) motion currently pending, there is no need for a temporary restraining order (“TRO”). “In deciding whether to issue a temporary restraining order, the factors to be weighed are *the same* as those to be weighed in deciding whether to enter a preliminary injunction.” *Mylan Pharms., Inc. v. Thompson*, 207 F. Supp. 2d 476, 484 (N.D. W. Va. 2001) (emphasis added); *see also Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp.*, No. 14-1268, 2014 WL 5088690 (D. Del. Oct. 9, 2014) (“A request for a TRO is governed by the same general standards that govern the issuance of a preliminary injunction.”). It is unnecessary for Regeneron to file a TRO motion when the Court already has before it Regeneron’s fully briefed PI motion requesting the same injunctive relief under the same legal standard.

Because TRO and PI motions both rely on the same four-factor test, Regeneron cannot prove entitlement to a TRO any more than it can prove entitlement to the extraordinary relief of a PI. SB respectfully submits that, instead of inviting Regeneron to file a TRO motion involving more pages and more argument about the same issues previously addressed in the PI motion, the Court can and should deny Regeneron’s PI motion for the reasons set forth in SB’s opposition to that motion (Dkt. 164-2).¹

¹ All Dkt. cites are to Civil Action No. 1:23-cv-94-TSK, unless otherwise indicated.

In particular, “a trial court may deny a [preliminary injunction] motion based on a patentee’s failure to show irreparable harm without analyzing the other factors.” *See Biogen Inc. v. Sandoz Inc.*, No. 22-1190, 2023 WL 7130655, at *5 (D. Del. June 29, 2023) (citing *Vertigo Media, Inc. v. Earbuds Inc.*, No. 21-120, 2021 WL 4806410, at *5 (D. Del. Oct. 14, 2021; *Jack Guttman, Inc. v. Kopykake Enterprises, Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002)). The “absence of irreparable harm ... ma[kes] unnecessary a consideration of... [the] likelihood of success in proving infringement.” *Ill. Tool Works, Inc. v. Grip-Pak Inc.*, 906 F.2d 670, 682 n.3 (Fed. Cir. 1990).

Indeed, in *Genentech, Inc. v. Amgen, Inc.* involving a PI and TRO motion in the BPCIA context, the court noted that “[d]ue to the hurried nature of this particular motion practice, I will not take additional time to set forth my analysis with respect to other preliminary injunction factors” beyond irreparable harm. No. 19-924, 2019 WL 3290167, at *3 (D. Del. July 18, 2019). Because the patent owner had “failed to establish irreparable harm,” the court denied its request for preliminary and temporary injunctive relief without considering any other factor. *Id.*

As in *Genentech*, in view of the impending May 18 deadline, the Court should deny Regeneron’s motion based on the lack of irreparable harm alone. While SB has shown that Regeneron has not established **any** of the four factors necessary to grant it a preliminary injunction (*see* Dkt. 164-2), Regeneron has completely failed to show any irreparable harm sufficient to justify the extraordinary preliminary relief it seeks. To satisfy the irreparable harm factor, Regeneron had the burden to establish two requirements: “1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement.” *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012)

(“*Apple II*”). Regeneron failed to establish either requirement, each of which serves as an independent basis for denying Regeneron’s PI motion or any follow-on TRO motion.

For example, as to nexus, the Court can reject Regeneron’s motion for a complete failure of proof. Regeneron offered *no* expert testimony or other evidence to support that the infringing features drive consumer demand, as required under the caselaw. Dkt. 164-2 at 16-19; *see Apple II*, 695 F.3d at 1375 (“It is not enough for the patentee to establish some insubstantial connection between the alleged harm and the infringement and check the causal nexus requirement off the list. The patentee must rather show that the infringing feature drives consumer demand for the accused product.”). Similarly, as to whether Regeneron will suffer irreparable harm absent an injunction, Regeneron likewise failed to present any reliable evidence to support this required element. Dkt. 164-2 at 19-25. Among other issues, Regeneron’s expert on irreparable harm based his analysis on a fundamental error regarding SB15’s average selling price (“ASP”) such that his conclusions and opinions are entirely unreliable. *Id.* When this error is corrected, the evidence shows that Regeneron is not likely to suffer any irreparable harm before trial, which is the relevant time period for the PI motion. *Id.* This is yet another independent ground for denying Regeneron any preliminary injunctive relief.

Thus, Regeneron has failed to meet its burden of proving it is entitled to any preliminary injunctive relief—whether via a PI or TRO. Because any TRO motion would suffer from the same defects as Regeneron’s PI motion, it would be futile to commence TRO proceedings when the fully briefed PI motion can and should be denied.

II. IF THE COURT PLANS TO ENTERTAIN A TRO MOTION, REGENERON SHOULD FILE WITH TIME FOR SB TO RESPOND

Should the Court nevertheless wish to entertain Regeneron’s TRO motion—or should Regeneron proceed to file one regardless, as it indicates it will—there is no reason for Regeneron

to wait until Tuesday May 14th, four days before EYLEA®'s regulatory exclusivity expires, to file. In proposing this date, Regeneron transparently seeks to delay its filing so that it may seek a TRO without providing SB time to respond. *See, e.g.*, Regeneron Mot. at 2 n.2 (asserting that the Court may grant TROs without opposition or oral argument). That is improper. Under Federal Rule of Civil Procedure 65(b)(1), Regeneron may seek a TRO without notice ***only if*** its attorneys “certif[y] in writing any efforts made to give notice and the reasons why it should not be required.” Regeneron cannot legitimately make any such certification. If Regeneron wants to move for a TRO, there is no reason it cannot do so as soon as possible so that SB can have a reasonable time to respond and the Court can have a reasonable time to issue its decision. Indeed, Regeneron identifies nothing in its Motion for Guidance preventing it from filing its proposed TRO sooner rather than later.

SB therefore proposes that if the Court wishes to entertain TRO briefing, Regeneron should be ordered to file any TRO motion no later than Wednesday May 8th, with SB's opposition due three business days later on Monday May 13th. SB's proposed timing provides substantially more time for an orderly proceeding, in which the Court can hear from both sides.

Dated: May 5, 2024

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appearing for the limited purpose of
contesting jurisdiction*

CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2024, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

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